

CLAIMS

What we claim is:

1. A macrophage infecting parasite expressing a granulocyte macrophage colony stimulating factor (GM-CSF) gene.
2. The parasite of claim 1 which is a strain of *Leishmania*.
3. The parasite of claim 2 wherein said strain of *Leishmania* is selected from the group consisting of *Leishmania donovani*, *Leishmania braziliensis*, *Leishmania tarentolae*, *Leishmania major*, *Leishmania mexicana*, *Leishmania tropica* and *Leishmania aethiopica*.
4. The parasite of claim 3 which is reduced in the ability of said strain to infect or survive within macrophages.
5. The parasite of claim 2 wherein said GM-CSF gene is of murine origin.
6. The parasite of claim 2 wherein said GM-CSF gene is of human origin.
7. The parasite of claim 2 wherein said GM-CSF gene is expressed using the α -tubulin intergenic sequences of *Leishmania enrietti*.
8. The parasite of claim 7 wherein said GM-CSF gene is expressed from a plasmid.
9. The parasite of claim 1 wherein at least one gene of the parasite contributing to virulence thereof has been functionally disabled.
10. The parasite of claim 1 which expresses at least one additional cytokine.
11. An immunogenic composition comprising an attenuated form of the parasite of claim 1.
12. The immunogenic composition of claim 11 wherein the parasite is a strain of *Leishmania* and the composition is formulated for *in vivo* administration to a host infected by *Leishmania* to treat said infection.

Sub A1

Sub A2

Sub A3

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13. The immunogenic composition of claim 11 wherein said parasite is a strain of *Leishmania* and said composition is formulated as a vaccine for in vivo administration to a host to confer protection against disease caused by a virulent strain of *Leishmania*.

14. The immunogenic composition of claim 13 wherein the virulent strain is selected from the group consisting of *Leishmania donovani*, *Leishmania braziliensis*, *Leishmania tarentolae*, *Leishmania major*, *Leishmania mexicana*, *Leishmania tropica* and *Leishmania aethiopica*.

15. The immunogenic composition of claim 12 or 13 wherein the host is a primate.

16. The immunogenic composition of claim 12 or 13 wherein the host is a human.

17. A method of generating an immune response in a host comprising administering thereto an immunoeffective amount of the immunogenic composition of claim 11.

18. A method for producing a vaccine for protection against a disease caused by infection by a virulent strain of a macrophage-infecting parasite, comprising:

administering the immunogenic composition of claim 11 to a test host to determine an amount and frequency of administration thereof to confer protection against the disease; and
formulating the immunogenic composition in a form suitable for administration to a treated host in accordance with said determined amount and frequency of administration.

19. The method of claim 18 wherein said parasite is a strain of *Leishmania*.

20. The method of claim 19 wherein the treated host is a human.

Add A⁴

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